2018 Current Fiscal Year Report: National Mammography Quality Assurance Advisory Committee

Report Run Date: 06/05/2019 12:09:41 PM

1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2018
3. Committee or Subcommittee	**3b. GSA Committee No.**
National Mammography Quality Assurance Advisory Committee	1671

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	07/07/2017	07/07/2019	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Statutory (Congress Created)

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
42 U.S.C. 263(b)	07/06/1991	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open 0 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 0

Meetings and Dates

No Meetings

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$0.00	$8,203.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$52,215.00	$94,456.00
18a(4). Personnel Pmts to Non-Member Consultants	$0.00	$0.00
18b(1). Travel and Per Diem to Non-Federal Members	$0.00	$13,760.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$0.00	$0.00

18c. Other(rents,user charges, graphics, printing, mail, etc.)	$13,054.00	$31,946.00
18d. Total	$65,269.00	$148,365.00
19. Federal Staff Support Years (FTE)	0.30	0.60

20a. How does the Committee accomplish its purpose?

The National Mammography Quality Assurance Advisory Committee (NMQAAC) provides advice to the Agency on the following tasks: (1) developing appropriate quality standards and regulations for mammography facilities, (2) developing appropriate standards and regulation for bodies accrediting mammography facilities, (3) developing regulations on sanctions, (4) developing procedures to monitor compliance with standards, (5) establishing a mechanism to investigate consumer complaints, (6) reporting new developments concerning breast imaging that should be considered in the oversight of mammography facilities, (7) determining whether there is a shortage of mammography facilities in rural and health professional shortage areas, (8) determining whether there will be a sufficient number of medical physicists after 1999, and (9) determining the costs and benefits of compliance with these requirements.

20b. How does the Committee balance its membership?

The Mammography Quality Standards Act of 1992 (MQSA) specifies that advisory committee members be selected from physicians, practitioners and other health professionals whose clinical practice, research specialization, or professional expertise includes a significant focus on mammography. The Act also directs the appointment of four individuals from among national breast cancer consumer health organizations with expertise in mammography and at least two practicing physicians who provide mammography services. The current committee is composed of M.D.'s and Ph.D's who have expertise in the fields of medical physics, teleradiology, medical physicist, digital mammography, and diagnostic radiology. Consumer interests are represented by mammographers, radiologic technologists and health education specialists.

20c. How frequent and relevant are the Committee Meetings?

This committee is mandated by the Mammography Quality Standards Act of 1992 (MQSA) to provide input in the promulgation of reasonable policies to execute the Act. Meetings are to be held annually.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

Committee members have backgrounds in academia, research, and/or clinical practice. Their advice and input lends credibility to regulation decisions made and assists those decisions to stand up to intense public scrutiny. The alternate means of accessing this

advice would involve the recruitment of large numbers of scientists on a full-time basis at maximum rates of compensation.

20e. Why is it necessary to close and/or partially closed committee meetings?

N/A

21. Remarks

Although this committee did not meet in FY 2018, considerable time was devoted to reappointing current members, maintaining associated records for these activities, and streamlining paper processes within FDA. In addition, time was spent in the routine care and maintenance of the committee: the development of a financial report for this website; updating the roster and number of vacancies on our website; completing the annual ethics report; reviewing financial disclosures of current members and providing ethics training. Since the Committee did not meet, no reporting was required.

Designated Federal Officer

Sara Anderson Senior Regulatory Review Officer, Center for Devices and Radiological Health/FDA

Committee Members	Start	End	Occupation	Member Designation
Barke, Lora	02/01/2016	01/31/2020	Medical Dir., Invision Sally Jobe. Greenwood Village, CO	Special Government Employee (SGE) Member
Berns, Eric	02/01/2016	01/31/2020	Assistant Professor, Dept. of Radiology, Denver Health Med. Ctr. & Univ. of CO at Denver	Special Government Employee (SGE) Member
Engebretson, Rhonda	05/31/2017	01/31/2021	Breast Imaging Navigator, Avera Breast Center, Sioux Falls, SD	Special Government Employee (SGE) Member
Geiser, William	02/01/2016	01/31/2020	Sr. Medical Physicist, Dept. of Imaging Physics, Univ. Texas MD Anderson Cancer Ctr., Houston, TX	Special Government Employee (SGE) Member
Goodsitt, Mitchell	02/19/2015	01/31/2019	Prof. of Biomedical Engineering, Dept. of Radiology, Univ. of Michigan Health System, Ann Arbor, MI	Special Government Employee (SGE) Member
Hitzelberger, Ronald	08/16/2016	01/31/2018	Project Mgr., R&DImaging IT Product Mgmt., Agfa Healthcare, Greenville, SC	Representative Member
Johnson, Judith	09/27/2017	01/31/2021	Consumer Represenrative;Breast Cancer Patient Advocate, St. Louis, MO	Special Government Employee (SGE) Member
Miller, Louise	09/27/2017	01/31/2021	CONSUMER REPRESENTATIVE: Dir. of Education, Mammography Educators, San Diego, CA	Special Government Employee (SGE) Member
Newell, Mary	02/19/2015	01/31/2019	Assoc. Prof. of Radiology, Emory University Hosp., Breast Imaging Ctr., Atlanta GA	Special Government Employee (SGE) Member
Portis, Natalie	02/01/2016	01/31/2019	CONSUMER REPRESENTATIVE: Clinical Psychologist, Oakland, CA	Special Government Employee (SGE) Member

Rosenberg, Robert	02/19/2015	01/31/2019	Staff Radiologist, Med. Dir. of Breast Imaging, Radiology Assoc. of Albuquerque, Albuquerque, NM	Special Government Employee (SGE) Member
Thompson, Jared	02/21/2017	01/31/2021	Program Mgr., AR Dept. of Health, Radiation Control Section, Little Rock, AR	Special Government Employee (SGE) Member
Torrente-Lagan, Jessica	02/19/2015	01/31/2019	Medical Staff, George Washington Comprehensive Breast Ctr., Washington,DC	Special Government Employee (SGE) Member
Tuttle, Deborah	08/16/2016	01/31/2020	CONSUMER REPRESENTATIVE, Oncology Nurse Practitioner, CA Oncology of the Central Valley (Fresno), Fresno, CA	Special Government Employee (SGE) Member
Uriell, Diane	08/16/2016	01/31/2020	Sr. Dir., Global Reg. Affairs XR and Woman's Health, GE Healthcare, Atlanta, GA	Representative Member

Number of Committee Members Listed: 15

Narrative Description

FDA's strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The National Mammography Quality Assurance Advisory Committee (NMQAAC) supports FDA's strategic priorities by advising the Food and Drug Administration on the following items, thereby helping FDA meet Objective 3 of Empowering Consumers by improving and increasing FDA-initiated health benefit/risk information:(A)developing appropriate quality standards and regulations for mammography facilities; (B)developing appropriate standards and regulations for bodies accrediting mammography facilities under this program; (C)developing regulations with respect to sanctions;(D)developing procedures for monitoring compliance with standards;(E)establishing a mechanism to investigate consumer complaints;(F)reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities;(G)determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas; (H)determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and (I)determining the costs and benefits of compliance with these requirements.

What are the most significant program outcomes associated with this committee?

Checked if Applies

Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	✓
Effective grant making	
Improved service delivery	
Increased customer satisfaction	✓
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments

NA

What are the cost savings associated with this committee?

	Checked if Applies
None	
Unable to Determine	✓
Under $100,000	
$100,000 - $500,000	
$500,001 - $1,000,000	
$1,000,001 - $5,000,000	
$5,000,001 - $10,000,000	
Over $10,000,000	
Cost Savings Other	

Cost Savings Comments

The utilization of the National Mammography Quality Assurance Advisory Committee enables the Agency to obtain required and frequently scarce professional services from medical and scientific experts not otherwise available to the Agency; and to obtain the services of these experts only on an as needed basis rather than on a full time basis . The service of the Committee resulted in advice for the improvement of the public health, for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?

87

Number of Recommendations Comments

The committee made 87 recommendations from FY03 through FY18---See question 20a

of the annual report or specific accomplishments

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
84%

% of Recommendations Fully Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA often accepts the recommendations from its committees, the advice is purely advisory in nature, therefore, the Agency has the option of not implementing the advice.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
15%

% of Recommendations Partially Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?
Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments
Most of the committee’s recommendations deal with guidance. When the guidance has been finalized, the committee is sent copies of the guidance.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☑
Reallocated resources	☐
Issued new regulation	☑
Proposed legislation	☐
Approved grants or other payments	☐
Other	☑

Action Comments

Issued new or modified guidance.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	✓
Online Agency Web Site	✓
Online Committee Web Site	✓
Online GSA FACA Web Site	✓
Publications	✓
Other	

Access Comments

N/A